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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,034	08/16/2000	Toshiyuki Yoneda	BEAR-006	3757

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EXAMINER

MAYES, LAURIE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/641,034

Applicant(s)

YONEDA ET AL

Examiner

Laurie Mayes

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-- The MAILING DATE of this communication appears on th cover sh t with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 6,10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9 and 12-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 1819
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

In view of the amendment filed on July 9, 2003, the objection to claims 6, 7 and 9 and the rejection of claims 8-15 under 35 U.S.C. 112 are withdrawn.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language "in naturally occurring protein matrix extracellular phosphoglycoprotein" is vague as it is unclear how a naturally occurring protein would differ from a synthetically made protein.

#### ***Allowable Subject Matter***

Claims 7 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 12, 13, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (US 5,849,865). Cheng et al. teach a composition comprising a peptide consisting

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of about 15 amino acid residues in length (see claim 1 and SEQ ID NOS: 33, 34 of Cheng et al., for example)(present claim 4) in the L-conformation (see Fig. 3)(present claim 5) wherein the peptide comprises the integrin binding motif RGD (SEQ ID NOS: 33, 34 of Cheng et al)(present claim 2), wherein the amino acid sequence is contiguous with the RGD sequence in the osteopontin phosphoglycoprotein (see Fig. 13, col. 2, line 67; col. 3, lines 1-10 and col. 22, lines 13+)(present claim 3) and wherein the peptide enhances bone growth (col. 15, lines 17-30)(present claims 1, 8). The composition also comprises a saline carrier (col. 14, lines 25-32) that is injectable (col. 15, lines 16-30)(present claims 12, 13, 16). Cheng et al. teaches all of the elements of claims 1-5, 8, 12, 13, 16 and these claims are rejected under 35 U.S.C. 102(b).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. in view of Cerny et al. (US 6,300,062). Cheng et al. teach a composition comprising a peptide consisting of about 15 amino acid residues in length (see claim 1 and SEQ ID NOS: 33, 34 of Cheng et al., for example)(present claim 4) in the L-conformation (see Fig. 3)(present claim 5) wherein the peptide comprises the integrin binding motif RGD (SEQ ID NOS: 33, 34 of Cheng et al)(present claim 2), wherein the amino acid sequence is contiguous with the RGD sequence in the osteopontin phosphoglycoprotein (see Fig. 13, col. 2, line 67; col. 3, lines 1-10

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and col. 22, lines 13+)(present claim 3) and wherein the peptide enhances bone growth (col. 15, lines 17-30)(present claims 1, 8). The composition also comprises a saline carrier (col. 14, lines 25-32) that is injectable (col. 15, lines 16-30)(present claims 12, 13, 16). Cheng et al. do not teach a composition that is a toothpaste or a mouthwash.

Cerny et al. (US 6,300,062) the administration of both mouthwash and toothpaste comprising an RGD peptide in promoting bone growth (col. 15, lines 20-37) and flavoring oils (col. 16, lines 5-20)(present claims 14, 15). Cerny et al. do not teach a peptide that is about 15 to 35 amino acids in length.

Given the advantages of administering the RGD peptide taught by Cheng et al. to promote bone growth the use of RGD peptides in mouthwash and flavored toothpaste to promote bone growth as taught by Cerny et al., it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to use the RGD peptide taught by Cheng et al. in a toothpaste or flavored mouthwash to promote bone growth and maintain healthy teeth. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Claims 1-5, 7-9, 12, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. as applied to claims 1-5, 8, 12, 13 and 16 above, and further in view of Rowe et al. (Genomics, V. 67, (1) (July 2000), pp. 54-68). Rowe et al. teach an RGD region consisting of about 22 amino acid residues in the L-conformation wherein the peptide comprises the integrin binding motif RGD and the amino acid sequence is contiguous with a sequence of naturally occurring matrix extracellular phosphoglycoprotein (MEPE) (see Fig. 1 and p. 60, col. 2, last four lines and see abstract). Given the advantages of administering a peptide comprising

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RGD as taught by Cheng et al. to promote bone growth, it would have been obvious to one of ordinary skill in the art to create an isolated peptide from the specific region taught by Rowe et al (amino acid residues 242-264; see Fig. 1) for use in promoting bone growth. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

***Conclusion***

**Claims 1-5, 8 and 12-16 are rejected. Claims 7 and 9 are objected to. No claims are allowed.**

US 2002/0102641 A1 (Schiavi et al.) and WO 01/72826 (Schiavi et al.) are noted of record as teaching a peptide of 19 amino acid residues in length and with a high sequence identity to SEQ ID NO: 44 (see SEQ ID NO: 6 in the cited references) that is administered to promote bone growth.

***Conclusion***

**Claims 1-5, 7-9 and 12-16 are rejected.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

*L. Mayes*

Laurie Mayes  
Patent Examiner  
Art Unit 1653  
August 21, 2003

*Christopher S. F. Low*

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